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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,933	12/31/2003	Dilip G. Saoji	U 014338-7	6675

7590 05/02/2007

Ladas & Parry
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EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
05/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/749,933	SAOJI ET AL.	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-55* is/are pending in the application.

4a) Of the above claim(s) *22-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38- 55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The response filed **1/22/07** presents remarks and arguments to the office action mailed **9/22/07**. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

Applicants' arguments, filed, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 39-55 recite the limitation "of claims that have been cancelled". There is insufficient antecedent basis for this limitation in the claim.

New Claim Rejections - 35 USC § 112

Claim 51 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims recite antifungal agents of polyenes, allyamines, imidazoles, thiocarbamates and triazoles.

A lack of adequate written description issue arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species); In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967).

An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.

A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]."

Applicant has not provided a description of the structure of a representative number of compounds nor a description of the chemical and/or physical characteristics of a representative number of compounds nor a description of how to obtain a representative number of specific compounds. For example taking compounds of imidazoles, there are numerous compounds of this classification.

In other words, the Applicant has not described with sufficient clarity what the above group of compounds are.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

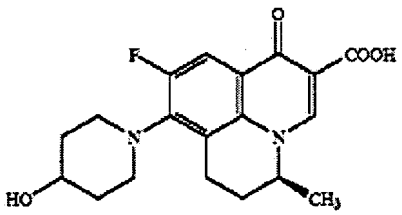
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims **38-45 and 54-55** are rejected under 35 U.S.C. 103(a) as being obvious over de Souza et al. US 6,514,986 in view of de Souza et al. US 6,608,078 B2 taken with Leyden J. Euro. Academy of dermatology and venereology15 (suppl.3). 51-55.

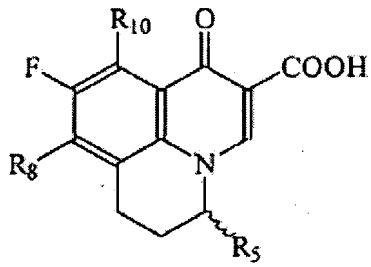
The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed

in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

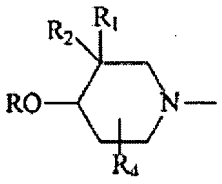
De Souza et al. ('986) teach a stable pharmaceutical composition comprising an aqueous carrier having in solution therein a benzoquinolizine-2-carboxylic acid



having the core chemical structure



as that disclosed in the instant claim 38 (see col. 4, lines 15+) that is an optical active isomer, in a pharmaceutically acceptable salt arginine singly or combined with other active agent such as antibacterial agents (see col. 8, lines 32+). Note although, the reference did not teach using any particular drug combination as cited in claim 38, the teaching is inclusive of a steroid, antifungal anti-

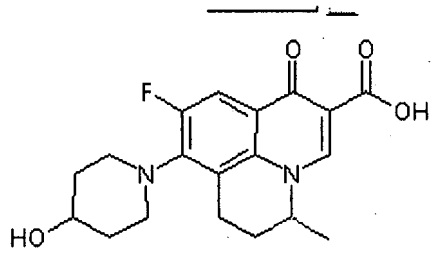
inflammatory because the reference teaches that the compound can be combined with other active agents and based on the type of disease for example if patient is suffering from pain an inflammatory active agent will be administered with the claimed compound. Thus the information from the reference is within the skill of one of ordinary skill in the art. With regards to R_5 is CH_3 (C=1) and R8 is  is shown in the above structure, where R_1, R_2 R_4 are hydrogen. As to claims 39 and 40-41 the benzoquinolizine-2-carboxylic acid antimicrobial drug is S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin- 1-yl)-5-methyl- 1-oxo- 1H,5H- benzo(ij)quinolizine-2-carboxylic acid (see abstract) the drug is used to treat antimicrobial infection and the arginine salt form in claim 4 (see col. 5 lines 20+), wherein the pharmaceutically acceptable salt if from an acid (see col. 2, lines 1+) as in claim 55 having a physical form of a cream (see col. 8, lines 35+)as in claim 21.

With regards to claim 38, the reference teaches ('078) a stable pharmaceutical composition having the core structure of the claimed invention (see col. 5, lines 25+), wherein the benzoquinolizine-2-carboxylic acid antimicrobial drug is S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin- 1-yl)-5-methyl- 1-oxo- 1H,5H- benzo(ij)quinolizine-2-carboxylic acid and the arginine salt form in claim 4 (see col. 8 lines 11+) wherein the pharmaceutically acceptable salt if from an acid (see col.6 lines 65+) as in claim 55 having a physical form of a cream (see col. 14, lines 1+)as in claim 21. The reference

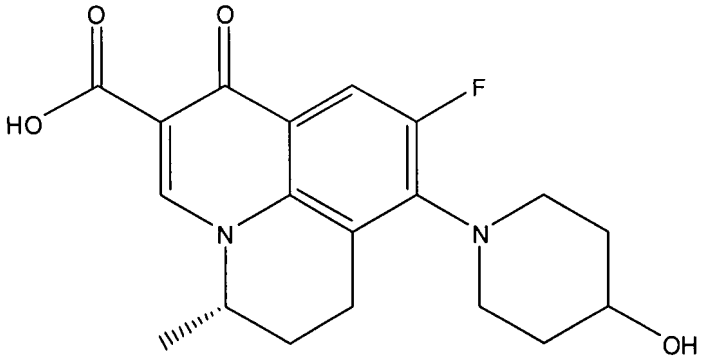
teaches addition of inorganic basic salts (see col. 6, line 55-57) as in the instant claim 54.

As to claims 42-44, the reference teaches the benzoquinolizine –2- carboxylic acid comprises 0-1 to 10% of the compound (see col. 15, lines 1-6)

Leyden teaches that antimicrobial agents nadifloxican-



(same drug as the claimed compound



S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin- 1-yl)-5-methyl- 1-oxo- 1H,5H- benzo(ij)quinolizine-2-carboxylic acid

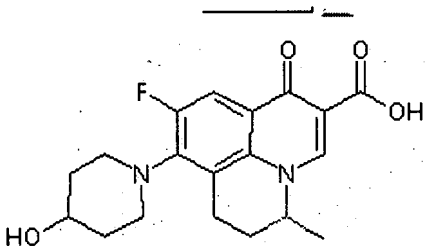
Caution: Stereochemical terms discarded: -

) are used in combination therapy with retinoids as in claim 45 (see abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare the above taught composition for the purpose of treating microbial infections (microbial infection such as fugal infection) having the above-cited reference and include a retinoid to the said formulation as an adjuvant therapy because it is known in the art that retinoids are used in medicine, primarily due to the way they regulate epithilial cell growth especially in the regulation of

cell proliferation in inflammatory skin disease. Although, the combined references did not expressly state the kind of retinoid agent to be used, one of ordinary skill in the art would be motivate to choose any of the retinoid agents in the claimed invention as expect a successful result in doing so because these agents are well know as antimicrobial agents and have been used in many formulation. Thus, the claimed invention was prima facia obvious to make and use at the time it was made.

Claims **45 and 51-52** are rejected under 35 U.S.C. 103(a) as being obvious over de Souza et al. US 6,514,986 taken with de Souza et al. US 6,608,078 B2 in view Leyden J. Euro. Academy of dermatology and venereology15 (suppl.3). 51-55 as applied to claims **38-45 and 54-55** above, and further in view of Katsambas et al. Clinics in Dermatology 2000; 18:171-176.

Katsamnas et al. teach treatment indications of acne, perioral dermatitis, wherein antimicrobials have been used-thus the claimed compound is an antimicrobial drug (nadifloxacin-  (see page 171-highlighted), anti-inflammatory agents (see page 171-highlighted), retinoids (isotretinoin as in claim 45 see page 172-highlighted), antifungal agents such as ketoconazole as in claims 51-52 (see page 172-highlighted) and steroids as hormones all have been used to treat acne.

The reference did not however teach the use together, but Leydon teaches that the compound is used with a retinoid agent for the treatment of dermatological

diseases, therefore, one of ordinary skill in the art would be motivated to use agents that have been known to individually treat the same disease condition.

The motivation to combine can arise from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Section MPEP 2144.07. Examiner notes that the particular drugs in claims 46, 47-50 and 53 are not taught.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SVG
4/9/07

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER